



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/628,803 07/28/00 MURPHY

J 112910.3302

EXAMINER

HM22/0410

PEPPER HAMILTON LLP
GILBERTO M VILLACORTA PH D
600 FOURTEENTH STREET NW
WASHINGTON DC 20005-2004

HUI, S	
ART UNIT	PAPER NUMBER

1617

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/628,803	Applicant(s) MURPHY ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicant's cancellation of claims 21-32 in Paper No.4, received March 14, 2001, is acknowledged.

Applicant's election with traverse of the invention of Group I, claims 1-20 and 33, and the species pagoclone in Paper No. 4, received March 14, 2001 is acknowledged. The traversal is on the ground(s) that there is not a serious burden imposed on the Examiner to search the subject matter covered by all claims herein. This is not found persuasive because the fields of search for all inventions are diverse. Note that the search fields for unrelated compositions is diverse. The composition of Group I has one active ingredient and the composition of Group II has two active ingredients. Furthermore, the search field for a composition containing certain ingredients is different from the search field for a particular method of use employing a composition containing the same ingredients. The search is not limited to the patent files. The inventions of Group I, II, and III are separate and distinct as discussed in the restriction requirement of Feb. 14, 2001. The search for all compositions and methods encompassed by the claims presents an undue burden to the Office as discussed in the restriction requirement mailed February 14, 2001.

Therefore, the requirement is still deemed proper and is made FINAL.

The claims have been examined herein to the extent they read on the elected invention and species.

Claim Rejections - 35 USC § 103

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourzat et al. (USPN 4,960,779 from the Information Disclosure Statement received March 14, 2001) and Doble et al. (J Pharmacol Exp Ther 266(3):1213-26 from the Information Disclosure Statement received March 14, 2001) in view of Novo Nordisk (English abstract of Denmark Patent DK9800727 from the Information Disclosure Statement received March 14, 2001) and Sandyk (Abstract from International Journal of Neuroscience, 1995, 83(1-2): 81-92; Medline, AN:96357641).

Bourzat et al. teaches a method of administering pyrrole compounds including pagoclone in a dose of 10 to 500mg daily (See claim 11 and 12; also col. 20, line 3-5 and 28-30). Bourzat et al. teaches that the routes of administration of the pyrrole compounds including pagoclone may be oral, rectal, parenteral, and percutaneous (See col. 19, lines 28-29).

Doble et al. teaches that pagoclone is a partial agonist of GABA_A receptor (see page 1224, col.2, first paragraph and page 1225, first col., last paragraph).

However, the primary references do not expressly teach the administration of pagoclone in methods of treating stuttering. Also, the references do not expressly teach the dosage of pagoclone herein.

Novo Nordisk teaches that stuttering is a disorder which is related to GABA-uptake activity (See abstract).

Sandyk teaches that the immediate improvement of dysarthria stuttering is the result of changes in the synthesis and release of GABA.

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to administer pagoclone to a patient in a method to treat stuttering.

One of ordinary skill in the art would have been motivated to administer pagoclone in a method to treat stuttering because the release of GABA_A or the increase of GABA_A levels are known to be associated with dysarthria and stuttering in the prior art. Therefore administering to patients suffering from stuttering any known GABA_A modulator including the elected compound, known to increase the GABA_A level, would be expected to produce beneficial effects in the treatment of a patient suffering from stuttering or dysarthria.

The optimization of result effect parameters (e.g., dosage range and dosage regimen) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

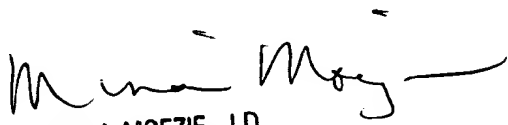
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

Art Unit: 1617

308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
April 9, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800